

Interview: C.Y. Cheng, Chairman, Formosa Laboratories, Taiwan



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Formosa Laboratories is one of Taiwan's international pioneers in small molecules, entering the global arena at a very early stage. How did that decision come about?

Generally speaking, Taiwan's API industry decided to go global long before the formulation sector did. The reason is simple: the local market for APIs is, and has always been, relatively small. For Formosa, international export was built into our strategy from an early stage, whereas most of our local peers in formulation have only recently been 'forced' into the global arena by increasingly difficult drug price controls at home.

Formosa was established in 1995. Because of the abundance of great research chemists in Taiwan, we started out as a contract research laboratory. However, we noticed that many of our customers wanted to utilize our services to develop APIs—so after a few years, we decided to go one step further, and produce those APIs ourselves. By 2000, our cGMP manufacturing facility came online in Taoyuan, northwestern Taiwan. We began to compete with API producers from around the world.

What gives Taiwanese companies an international edge in the API space?

Because of the limitations I mentioned in the local market, we quickly learned to match an international standard of quality. Taiwanese API companies are relatively small, but in terms of compliance with GMP protocols, we are excellent. Taiwan also has a great image in terms of IP protection, which means our partners can trust us.

We maintain a competitive edge in research and development as well. Formosa, for instance, has come up with a number of innovative API processes that can either bypass the originator's patent or warrant the granting of a new patent. We have been successful in attracting the attention of a number of generic players that are facing patent challenges. Generic companies want to be 'first to file,' and Formosa has supported a couple of dozen ANDA filings in the US to date.

To what extent are you concerned about the rise of low-cost API players in countries like India and China?

Indian companies do indeed pose a challenge for us—much more so than the Chinese even. India is considerably more advanced than China in terms of GMP compliance and Western-focused business strategy. Approximately 70-80 percent of the generic formulations sold in the US are made in India. The market for large-volume products is of course largely driven by price, and we know we cannot compete on price. We try to avoid head-to-head battles with Indian companies by focusing on the more complicated molecules.

China, actually, is not a threat but rather a boon for us. The advancement of China's API industry has given us the opportunity to source a major part of our intermediates and raw materials from our neighbor. The Chinese are capable of producing the majority of the API, but, lacking GMP compliance, they often need to pass the product onto a company like Formosa to complete the GMP steps and market the final chemical.

It has been said that Taiwan may be the only place in the world where pure API companies have decided to go public. Why do you think that is?

The capital market in Taiwan is very healthy. Its resources are limited, but it has a strong evaluation system and offers an opportunity for even small enterprises to get listed.

And it's not just the public market that is good for business: the interest rates in this country are quite attractive as well. For companies that want to borrow money from the bank, that is good news. Formosa has never had any major difficulty in getting a loan.

Other companies have begun to branch out into areas like formulation. What development strategies is Formosa implementing?

Our current focus is on making our API portfolio more complete. The way we have looked to do this is through partnership, rather than ownership. For instance, we are now actively developing a line of fermentation products through an alliance with a southern Taiwanese collaborator. We are also becoming involved in proteins: we recently won a bid for the Development Center for

Biotechnology (DCB)'s protein pilot plant facility and orchestrated the formation of a new bio-tech company EirGenix.

For now, we are a major shareholder in EirGenix, which will operate the facility, but with time, we will develop a full strategic alliance that can work in areas like Antibody Drug Conjugates (ADC). Formosa already has a great high-potency API facility, and by leveraging this facility in combination with EirGenix's protein capabilities, we can offer services and also work on our own new drug or biosimilar pipeline in the ADC field.

We haven't thought of working on formulation for its own sake, but our expansion into formulations is possible. Some of our fermentation products, for example, may be better off if we bring them to a finished product stage before they leave our doorstep. It is possible that we will get involved in formulation to a limited extent.

Personally, I am particularly interested in new drug development, and involved in two projects in which we have already invested are a strategic partner. We are also a founding shareholder of TaiRx, which has a very promising compound under development. If it reaches the market, we will enjoy both holding benefits and a revenue stream as the API supplier for the drug. Another compound we are involved with belongs to Taipei Medical University (TMU). We are the only industrial sponsor on the project, and I think this drug too looks quite promising. We will file the IND by the middle of next year.

How does diversification fit into your vision for Formosa's role in the market?

I don't want to turn Formosa into an integrated pharmaceutical company. However, I think that we are in a good position to get involved in a number of carefully selected drug development projects. We can help carry these products to commercialization, or perhaps find an attractive exit down the road. As we discussed, the capital market in this country is quite favorable right now, particularly for drug development companies.

Of course, we don't know how sustainable this enthusiasm is. But either way, I see innovation as a good route for Taiwan. The majority of drug candidates fail, so you need a big portfolio of potential compounds to eventually land on a winner. Every Taiwanese company that wants to participate has to help carry that burden, and eventually they can share in the spoils. We have to think of Taiwan Inc.'s broader pipeline, and we all have to consider where we can get in, where we can get out, and what value we can offer.

Does Taiwan Inc. have anything to celebrate yet in biotech?

We are not quite there yet. Our inherent weakness is that we are small. We hope the industry and the government can work together to make this island more modern, and more international. We hope that Taiwan can do better in the educational system, which does not do enough to teach our young people concrete industrial skills. We hope that we can attract more foreign talent, and more foreign money.

It is also important that we find our identity, and we should start with our political identity. We cannot depend too much on China. If we talk about 'Taiwan Inc.', we first have to figure out exactly *what* it is that we're talking about.

At the moment, Formosa is working to strengthen its infrastructure. Until recently, we kept our capital relatively low—but now, as we look for additional growth, we have to invest more in our capacity. We are ready to scale up significantly over the next five years.

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